

8/13/04

**Comments Regarding Docket No. 97N-484R**

Section 1271.85(b)(2)

Guidance Doc V (B)(1)(b) pg 32-33

**CMV status for reproductive donors:**

Page 29802: Recommended language: **It is the responsibility of the tissue bank to provide with each HCT/P the CMV reactive status of the semen donor.**

Section 1271.90(b)

Guidance Doc VII page 37-38

**Labeling**

**Units of reproductive tissue, i.e vials and straws, are very small (< 1/4 inch diameter) with limited labeling surface area. There is room on the container to record the donor I.D#., date of donation, name of tissue bank and perhaps 5-6 other characters. Any other information about the specimen/donor must be provided on package inserts that accompany the tissue.**

**Retesting:**

**Anonymous semen/oocyte donors should be screened for exposure to HIV, HBC and HCV at the time of donation and no less than 6 months post donation using antibody screening. If the antibody tests are negative the gametes are deemed suitable for release.**

**Embryos:**

**HIV and HCV NAT testing of both gamete donors should be performed at the time of donation if the resulting embryo is designated for transplant into a recipient other than the oocyte donor. Alternatively, the donors should be tested for HIV, HBC and HCV no less than 6 months post donation.**

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